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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/911,423	08/14/97	GORMAN	D DX0612K1

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HM31/0511

EXAMINER	
TUNG, M	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/11/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/911,423

Applicant(s)

Gorman, et al.

Examiner

Mary Tung

Group Art Unit

1644



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ----- months, or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-22 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Effective February 7th, the Group and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1644, Group 1640, Technology Center 1600.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-5 and 12 drawn to the 312C2 protein, a fusion protein and composition, classified in class 530, subclass 350; class 424, subclass 185.1; class 514, subclass 21.
- II. Claims 6, 7 and 12 drawn to an antibody, classified in class 530, subclass 387.9.
- III. Claim 8, drawn to a method of purifying 312C2 protein, classified in class 530, subclass 413.
- IV. Claims 9-11, 12, 17, 19 and 20, drawn to a nucleic acid, vector, and a method of expressing 312C2 protein, classified in class 536, subclass 23.5, class 435, subclasses 69.1 and 320.1.
- V. Claim 13, drawn to a method for detecting 312C2 protein, classified in class 435, subclass 4.
- VI. Claims 14-16, drawn to a method of modulating a cell, classified in class 435, subclasses 69.1, 375 and 377.
- VII. Claim 18, drawn to a tissue, cell or organism, classified in class 435, subclasses 325 or 347, or class 800, subclass 2.
- VIII. Claims 21 and 22, drawn to a method of treating a mammal, classified in class 424, subclasses 139.1 or 185.1, or class 514, subclass 44.

3. Groups I, II, IV, V and VIII are unique products. They differ with respect to their physicochemical properties and are therefore patentably distinct.

4. Groups III, VI, VII and IX are unique methods. They differ with respect to ingredients and method steps. The method of purifying the 312C2 protein of Group III would not suggest the method for detecting 312C2 in a sample as recited in Group VI. Nor would the methods of Groups III and VI suggest the treatment of cells or mammals as recited in Groups VII or IX, respectively. Additionally, a method of treating a cell in Group VII would involve different steps, reagents and materials than a treatment of a mammal in Group IX. They are therefore, patentably distinct each from the other.
5. Because a search of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner.
6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
7. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121:
8. If Groups V, VI, or VIII are elected, the applicant is further required to elect a **specific embodiment**: protein, nucleic acid or antibody.
9. If Group VII is elected, the applicant is also required to elect a **specific embodiment**: tissue, cell, organ or organism.
10. If Group VI is elected the applicant is further required to elect a **specific modulation of physiology**: apoptosis of T cell or activation of T cell.
11. If Group VIII is elected, the applicant is further required to elect a **specific abnormal immune response**: T cell deficiency, chronic inflammation or tissue rejection.
12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
13. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
15. The following claim(s) are generic: claims 13-15, 18, 21-22.
16. The species are distinct each from the other for the following reasons:
17. The recited products, protein, antibody or nucleic acid have different biochemical characteristics, structure and functions.
18. The recited cell, tissue, organ or organism are different in their properties, morphological appearances and physiological function.
19. Apoptosis of T cells and activation of T cells are opposite cellular responses and would be measured using different reagents, steps and involve different cellular mechanisms.
20. T cell deficiency, chronic inflammation, and tissue rejection are different abnormal immune responses, with different etiologies, clinical presentations and treatment modalities.
21. A telephone call was made to Edwin Ching on April 30, 1998 to request an oral election to the above restriction requirement, but did not result in an election being made.
22. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
26. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Monday through Friday from 8:30 am to 5:30 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

Mary B Tung

May 7, 1998

Mary B. Tung, Ph.D.

Patent Examiner

Group 1640

Christina Chan

CHRISTINA Y. CHAN

SUPERVISORY PATENT EXAMINER

GROUP 1640